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Patent

Attorney's Docket No. 017753-154

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
Thérèse de BIZEMONT *et al.*) Group Art Unit: 3763
Application No.: 09/836,439) Examiner: Unassigned
Filed: April 17, 2001)
For: GENE THERAPY WITH CHIMERIC)
OLIGONUCLEOTIDES DELIVERED)
BY A METHOD COMPRISING A STEP)
OF IONTOPHORESIS)

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JUL 28 2002

TECH CENTER 1600/2900



INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98.

Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is enclosed.

U.S. Patents

4,141,359	Jacobsen et al.
4,250,878	Jacobsen et al.
4,301,794	Tapper
4,747,819	Phipps et al.
4,752,285	Petelenz et al.
4,915,685	Petelenz et al.
4,979,938	Stephen et al.
5,250,022	Chien et al.
5,374,242	Haak et al.
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5,730,716	Beck et al.
6,001,088	Roberts et al.
6,018,679	Dinh et al.
6,139,537	Tapper

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6,148,231	Henley
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Alain FISCHER et al "Gene Therapy of Severe Combined Immunodeficiencies" *Immunological Reviews* 2000, vol.178 (2000) pp.13-20 (Munksgaard, Denmark)

S. HACEIN-BEY et al., "yc Gene Transfer Into SCID X1 Patients' B-Cell Lines Restores Normal High-Affinity Interleukin-2 Receptor Expression and Function", *Blood*, vol. 87, No. 8 (1996) pp. 3108-3116 (Amer. Soc. Hematology, USA)

Kevin D. BUNTING et al, "Restoration of Lymphocyte Function in Janus Kinase 3-Deficient Mice by Retroviral-Mediated Gene Transfer", *Nature Medicine*, vol. 4, No. 1, (1998) pp. 58-64 (Nature America, Dist)

Claudio BORDIGNON et al, "Gene Therapy in Peripheral Blood Lymphocytes and Bone Marrow for ADA Immunodeficient Patients", *SCIENCE*, vol. 270, (1995) pp. 470-475 (Amer. Assoc. for the Adv. of Science, USA)

Donald B. KOHN et al., "T Lymphocytes With a Normal ADA Gene Accumulate After Transplantation of Transduced Autologous Umbilical Cord Blood CD34⁺ Cells in ADA-Deficient SCID Neonates", *NATURE MEDICINE*, vol. 4, No. 7 (1998) pp.775-780 (Nature America, USA)

Marina CAVAZZANA-CALVO et al, "Gene Therapy of Human Severe Combined Immunodeficiency (SCID) - X1 Disease", *SCIENCE*, vol. 288 (2000) pp. 669-672 (Amer. Assoc. for the Adv. of Science, USA)

Rafat ABONOUR et al, "Efficient Retrovirus-Mediated Transfer of the Multidrug Resistance 1 Gene Into Autologous Human Long-Term Repopulating Hematopoietic Stem Cells", *NATURE MEDICINE*, vol. 6, No. 6 (2000) pp. 652-658 (Nature America, USA)

David A. WILLIAMS, "Progress in the Use of Gene Transfer Methods to Treat Genetic Blood Diseases", *HUMAN GENE THERAPY*, vol. 11, (2000) pp. 2059-2066 (Mary Ann Liebert, Inc., USA)

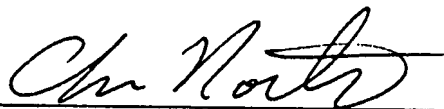
The documents are being submitted within 3 months of the filing or entry of the national stage of this application or before the first Office Action on the merits, whichever is later, therefore no fee or statement is required under 37 C.F.R. § 1.97(b).

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: _____



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Date: March 27, 2002

Substitute for forms 1449A/PTO & 1449B/PTO

ATTORNEY'S DKT NO.
017753-154APPLICATION NO.
09/836,439**SECOND INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**APPLICANT
Thérèse de BIZEMONT *et al.*FILING DATE
April 17, 2001GROUP
1635**U.S. PATENT DOCUMENTS**

Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
	5,760,012		Eric B. KMEC <i>et al.</i>	06-02-1998
	6,154,671		Jean-Marie PAREL <i>et al.</i>	11-28-2000

FOREIGN PATENT DOCUMENTS

Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	Translation Yes No

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	(Abstract only) STODULKOVA <i>et al.</i> , "Initial Test of Chimeraplasty in Correcting a Mouse Retinal Degeneration" IOVS, 2001, pg. S346, Vol. 42, No. 4, Annual Meeting of the Association for Research in Vision and Ophthalmology, Fort Lauderdale, Florida, USA, April 29 - May 4, 2001
	(Abstract only) DE BIZEMONT <i>et al.</i> , "Confocale Laser Scanning Microscopy of the Anterior Segment of the Rat and Mouse Eye after Iontophoresis of Fluorescent Antisense Oligonucleotides", IOVS, 2001, pg. S171, Vol. 42, No. 4, Annual Meeting of the Association for Research in Vision and Ophthalmology, Fort Lauderdale, Florida, USA, April 29-May 4, 2001
	ASAHARA <i>et al.</i> , "Induction of Gene into the Rabbit Eye by Iontophoresis: Preliminary Report", Japanese Journal of Ophthalmology, 2001, pgs. 31-39, Vol. 45, Japanese Ophthalmological Society, Elsevier Science, Inc., Oxford, ENGLAND
	SOHOCKI <i>et al.</i> , "Prevalence of Mutations Causing Retinitis Pigmentosa And Other Inherited Retinopathies", Human Mutation, 2001, pgs. 42-51, Vol. 17, No. 1, Wiley-Liss, Inc., New York, New York, USA
	OZAKI <i>et al.</i> , "Hypoxia Inducible Factor-1alpha Is Increased in Ischemic Retina: Temporal and Spatial Correlation with VEGF Expression", Investigative Ophthalmology and Visual Science, 1999, pgs. 182-189, Vol. 40, No. 1, Association for Research in Vision and Ophthalmology, Fort Lauderdale, Florida, USA
	PRÉAT <i>et al.</i> , "Topical Delivery of Nucleic Acids in the Skin", S.T.P. Pharma Sciences, 2000, pgs. 57068, Vol. 11, No.1, Société Française des Sciences et Techniques Pharmaceutiques, Paris, France
	KMEC <i>et al.</i> , "Targeted Gene Repair in Mammalian Cells Using Chimeric Oligonucleotides", Genetic Engineering, 2000, pgs. 23-31, Vol. 22, Plenum Press, New York, New York, USA
	ALEXEEV <i>et al.</i> , "Localized in Vivo Genotypic and Phenotypic Correction of the Albino Mutation in Skin by RNA-DNA Oligonucleotide", Nature Biotechnology, 2000, pgs. 43-47, Vol. 18, No. 1, Nature America, New York, New York, USA
	KMEC <i>et al.</i> , "Targeted Gene Repair - in the Arena", The Journal of Clinical Investigation, 2003, pgs. 632-636, Vol. 112, No. 5, American Society for Clinical Investigation, Thorofare, New Jersey, USA
	(Abstract only) BERDUGO <i>et al.</i> , "Delivery of Antisense Oligonucleotide to the Cornea by Iontophoresis", Antisense Nucleic Acid Drug Dev., 2003, pgs 107-114, Vol. 13, No. 2, Ipswich, Massachusetts, USA
	(Abstract only) KURZ <i>et al.</i> , "Novel Approaches for Retinal Drug Delivery", Ophthalmol Clin North Am., 2002, pgs. 405-10, Vol. 15, No. 3, W.B. Saunders Co., Philadelphia, Pennsylvania, USA
	VOIGHT <i>et al.</i> , "Down-regulation of NOSII Gene Expression by Iontophoresis of Anti-sense Oligonucleotide in Endotoxin-induced Uveitis", Biochemical and Biophysical Research Communications, 2002, pgs. 336-341, Academic Press, London, England
	(Abstract only) KEEN <i>et al.</i> , "Autosomal Dominant Retinitis Pigmentosa: Four New Mutations in Rhodopsin, One of Them in the Retinal Attachment Site", Genomics, 1991, pgs. 199-205, Vol. 11, No. 1, Academic Press, San Diego, California
	(Abstract only) ROBINSON <i>et al.</i> , "Constitutively Active Mutants of Rhodopsin", Neuron, 1992, pgs. 719-25, Vol. 9, No. 4, Cell Press, Cambridge, Massachusetts, USA
	LIANG <i>et al.</i> , "Optimizing the Delivery Systems of Chimeric RNA-DNA Oligonucleotides. Beyond General Oligonucleotide Transfer", Eur. J. Biochem, 2002, pgs. 5753-5758, Vol. 269, Blackwell Science, Berlin, Germany
	ROBINSON <i>et al.</i> , "Opsins with Mutations at the Site of Chromophore Attachment Constitutively Activate Transducin but Are Not Phosphorylated by Rhodopsin Kinase", Proc. Natl. Acad. Sci USA, 1994, pgs. 5411-5415, Vol. 91, National Academy of Sciences, Washington, D.C., USA
	International Search Report for corresponding International Application No. PCT/IB02/02310, dated April 14, 2003

Examiner Signature	Date Considered
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. **SEND TO:** Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Sheet 1 of 1

Application Number	09/836,439
Filing Date	April 17, 2001
First Named Inventor	Thérèse de BIZEMONT et al.
Examiner Name	Richard A. Schnizer
Attorney Docket Number	017753-154

[illegible][illegible]

Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	Charlotte ANDRIEU et al., "Genoplasty in the retina of rd1 mouse: Evidence for DNA correction and protein expression,"
	F. BEHAR-COHEN, "Recent Advances in Ocular Drug Delivery,"
	John B. DAVIES, et al., "Delivery of several forms of DNA, DNA-RNA hybrids, and dyes across human sclera by electrical fields," MOLECULAR VISION 9:569-578 (2003), Department of Ophthalmology, Atlanta, Georgia

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



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U.S. Patent No. 5,374,242

U.S. Patent No. 5,250,022

T. Asahara *et al.*, "Japanese Ophthalmological Society," Vol. 45, pp. 31-39 (2001)

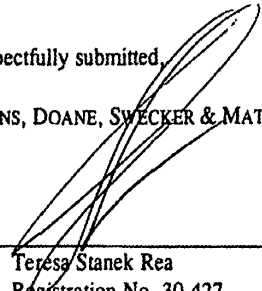
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Respectfully submitted,

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